lines 5-7, wherein it sates, "[DRG11] can be used as a molecular maker to identify neurons in the peripheral sensory lineage." Applicants submit that this utility is both "specific" and "substantial" in view of the Revised Interim Utility Guidelines.

The specification explains that sensory neuron-specific markers were not previously available (*see* page 2, lines 9-15). The specification details that expression of DRG11 mRNA and protein is specific to sensory neurons deriving from the neural crest and localizing in the dorsal root ganglia. As the skilled artisan knows, these neurons represent the sole avenue of fine somatic sensation to the brain, necessary not only for touch but also for proper motor control. Peripheral sensory neurons are not uncharacterized proteins, nor is this utility akin to disclosing a "gene probe" or "chromosome marker" in the absence of a disclosure of a specific DNA target.. The claimed nucleic acids are markers for this specific subset of neurons, not cells in general, or even neurons in general. Therefore, the utility of this invention is specific.

Furthermore, the utility of a marker for cells destined to be peripheral sensory neurons is "substantial", in fact "well established". Such markers can be used to obtain or isolate pools of such neurons. The skilled artisan will readily see the utility of such a marker in isolating peripheral sensory neurons for investigation of neurodegenerative diseases or neural injury, to name but two examples. This utility is not the same as merely allowing for further research to characterize the marker protein, nor is it the same as being directed to treating an unspecified disease. Identified and/or isolated peripheral sensory neurons have substantial utility. The ability to identify and isolate cells destined to become peripheral sensory neurons has applications in developing models of disease

and in drug discovery and testing. That the applicability of the utility is broad does not take away from its specificity, but only supports its substantiality.

For the reasons discussed above, the invention of Claims 1, 2, and 4-7 does have the requisite utility to satisfy the requirements of 35 U.S.C. § 101. Therefore, Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 112, first paragraph as not teaching how to make and use the invention due to lack of utility under 35 U.S.C. §101. As discussed above, the cited claims do satisfy the utility requirements. Therefore, Applicants respectfully request that this rejection be withdrawn

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 112, as not bing supported by a sufficient written description. Applicants respectfully traverse.

The Office Action states, "No written description is provided in the instant specification as to what constitutes nucleotide sequences comprising unknown and undescribed promoter sequences, ..." The Examiner appears to have been concerned that the claims encompassed in situ genomic DNA encoding the DRG11 protein, with all associated 5′ and 3′ sequences. The claims have been amended to specify that the nucleic acids are cDNA or recombinant nucleic acids, therefore all associated sequences are readily characterized by the skilled artisan, utilizing the teachings of the present specification and the general knowledge in the art.

For the reasons discussed above, Claims 1, 2 and 4-7 satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Therefore, Applicants respectfully request that this rejection be withdrawn.

In light of the above remarks, Applicants submit that the present application is in condition for allowance and respectfully request early notification of such.

Respectfully submitted,

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SF-1009479v1

APPENDIX

1. (Twice Amended) An isolated cDNA or recombinant nucleic acid encoding a DRG11 protein, wherein said cDNA or recombinant nucleic acid hybridizes under high stringency conditions to a complement of a nucleic acid molecule having a sequence as set forth in SEQ ID NO:1, and wherein said DRG11 protein is characterized by its natural expression in sensory neurons and dorsal horn neurons of the spinal cord and wherein its natural expression is absent in non-neuronal cells, sympathetic neurons and ventricular neurons of the spinal cord.

2. (Twice Amended) An isolated nucleic acid according to claim 1 encoding the amino acid sequence depicted in Figure 3 (SEQ ID NO:2).

4. (Twice Amended) An isolated nucleic acid according to claim 1 comprising the nucleic acid depicted in Figure 2 (SEQ ID NO:1).

5. (Amended) An isolated nucleic acid according to claim 1 operably linked to an expression vector comprising transcriptional and translational regulatory DNA.

6. A host cell transformed with an expression vector according to claim 5.

7. (Amended) A method of producing a DRG11 protein comprising:

a) culturing a host cell transformed with an expression vector comprising a nucleic acid according to claim 1; and

b) expressing said nucleic acid to produce a DRG11 protein.